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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,767	10/20/2003	Mark Hamm	21400/0209952-US0	4545
79292 7590 12/08/2009 Boston Scientific Corporation Darby & Darby P.C. P.O. Box 770 Church Street Station New York, NY 10008-0770				
EXAMINER				
LAMPRECHT, JOEL				
ART UNIT		PAPER NUMBER		
3737				
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12/08/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,767

Applicant(s)

HAMM ET AL.

Examiner

JOEL M. LAMPRECHT

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-10, 12-16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, 12-16 and 18-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 5, 7-10, 12-15, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being obvious over Ben-Haim et al (US 6,309,370 B1) in view of Hadjicostis et al (US 5,947,905) and in further view of Frey et al (US 2005/0042424 A1). Ben-Haim et al discloses an imaging catheter for use in intracardiac drug delivery including an imaging element at the distal end (Col 14 Line 25-40), an RF sensor located proximal thereto, and signal lines running over the RF sensor to the imaging device (Col 12 Line 10-Col 14 Line 15 Fig 4) for tracking of the medical instrument. Ben-Haim includes electrical

couplings which connect the imager and sensor to control circuitry and energy sources (Figure 4) and run over the RF sensor.

Ben-Haim discloses all that is listed above and also discloses the use of a sonolucent media in the lumen of the sheath (Figure 1, Col 1 Line 20-45) but fails to disclose the use of a coaxial cable for running the system in parallel with the sensor, a piezoelectric crystal and acoustic lens for imaging (though an ultrasound imaging system is disclosed in the tip of the device), or the use of a tungsten or epoxy material as the non-conductive backing material for the film layer.

Attention is then directed to the secondary reference by Hadjicostis et al which teaches the use of a coaxial cabling for parallel system functionality and signal fidelity (Col 7 Line 35- Col 8 Line 30, Col 5 Line 25-40), a piezoelectric film (Col 2 Line 55 - Col 3 Line 25) layer for acoustic imaging with a non-conductive backing layer (C1m 7, Col 5 Line 55-Col 6 Line 24), and the use of tungsten or epoxy material as a non-conductive backing layer and as a signal line layer (C1m 31, 32, Col 6 Line 10-25). Furthermore, Hadjicostis et al discloses an embodiment comprising a non conductive material disposed over the conductive primary layer or core which comprises the circuit coils and also discloses the use of multiple layers of traces which are formed at separate levels and are disposed in between solid dielectric layers (Col 8 Line 10-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the film and connection components of Hadjicostis et al with the system of Ben-Haim et al for the purpose of providing the best signal fidelity and clearest

diagnostic image possible as well as providing organizational bundling for circuit and signal elements.

Ben-Haim in view of Hadjicostis et al does not disclose traces being disposed **IN** the matching layers, rather Hadjicostis et al surround the trace layers with matching layers of dielectric materials. Attention is then directed to a teaching reference to Frey et al which specifically discloses that within non-conductive layers traces may be formed to allow for specific connections to be made within the stack (0028-0033, 0060-0065) and the use of epoxy layering to provide a non-conductive shell (0050-0052). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the layering circuitry of Frey with the system of Hadjicostis et al and the RF locating system of Ben-Haim for the purpose of allowing for maximum electrical connectivity while maintaining high signal-to-noise rate within a medical catheter.

Claims 6, 16, and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al in view of Hadjicostis et al and Frey et al as applied to claim 5 above and in further view of Webb (6,019,726). The removable sensor of Ben-Haim in view of the system of Hadjicostis et al and layering of Frey et al discloses all that is listed above, but fails to include a drive shaft surrounding the wiring to the sensor, as Hadjicostis et al relies on a non-mechanically driven system. Hadjicostis et al does disclose that such systems are known (Col 1 Line 39-Col 2 Line 4), but instead opts for an alternative method of an electronic imaging system. Attention is directed to the reference to Webb which incorporates a drive shaft, rotational transducer system including tracking circuitry for location and positioning of the transducer stack (Abs, Fig

1, Col 3 Line 25-55). As stated above, Hadjicostis et al acknowledges that mechanically driven transducers are indeed well-known and would be obvious to one of ordinary skill in the art at the time of the invention so long as methods like those of Webb (Col 3 Line 10-20) are taken to reduce the distortion induced by a mechanically driven transducer.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al in view of Hadjicostis et al and Frey et al as applied to claim 27 above and in further view of Proudian et al (US 4,917,097). Ben-Haim in view of Hadjicostis et al and Frey et al discloses all that is listed above but fails to mention the use of parylene as a non-conductive material for use within the device. Attention is then directed to the secondary reference by Proudian et al which discloses the use of parylene as a non-conductive transducer component for insulating and preventing shock to an electrical system (Col 8 Line 40-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized this parylene component rather than an epoxy (such as that of Hadjicostis et al) as the two provide the same functionality and insulating capabilities.

Response to Arguments

Applicant's arguments filed 8/24/09 have been fully considered but they are not persuasive. Applicant has argued that Ben Haim does not teach a sensor with inner core and outer coil(s). As mentioned by Applicant on page 8 paragraph 1 of arguments, Ben Haim discloses a position sensor and makes reference to a published WO application for further disclosure. Turning to that disclosure (also to Ben Haim), one finds that Fluxgate-type sensors are disclosed which include a solid core and coil(s)

wrapped around the core. Applicant has also argued that transducer elements or piezoelectric elements of an ultrasound system are not a "sensor", to which Examiner respectfully disagrees. Sensor or medical positioning sensor would encompass both imaging transducers and RF or magnetic/squid elements. While these sensors are not "coils" per-se, the inclusion of traces or epoxy on a sensor element intended for an in-vivo environment is surely taught by Frey and Hadjicostis. Finally, Applicant has argued that Webb does not disclose a sensor coil distal to a drive shaft coil. Webb in figure 1 discloses a sensor coil (Fig 2 ele 28) disposed distal to a drive-shaft coil.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JOEL M. LAMPRECHT** whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JML